112TH CONGRESS
1ST SESSION

S. 1584

To provide for additional quality control of drugs.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 20, 2011

Mr. BENNET introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide for additional quality control of drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Drug Safety and Accountability Act of 2011''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Recent manufacturing quality problems resulting in drug recalls and warnings from the Food and Drug Administration have exposed gaps in quality systems to ensure drugs in the United States are safe and free from contamination.

(2) Adherence to quality standards is the most effective way to ensure drug quality and integrity. It is impossible to test every pharmaceutical item that is produced.

(3) More than 1,300,000 over-the-counter children's medicines were recalled in 2010 for quality issues that presented possible risk to patient health, and the quality standards at many other over-the-counter manufacturers are unknown.

(4) Up to 149 Americans died in 2007 and 2008 after taking heparin, a blood thinner, contaminated during the manufacturing process in China.

(5) Up to 80 percent of the active ingredients in drugs used in the United States are made overseas, many in countries where regulatory oversight does not meet the standards of the United States.

SEC. 3. QUALITY CONTROL OF DRUGS.

(a) ADULTERATION.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by adding at the end the following:

''(j) If it is a drug that was manufactured, prepared, propagated, compounded, or processed by an establishment that is, or was at the time of such manufacture, preparation, propagation, compounding, or processing, in violation of subsection (q) or (r) of section 510.''.

(b) ADDITIONAL REQUIREMENTS OF PRODUCERS OF DRUGS.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following:

''(q) QUALITY MANAGEMENT PLANS.—

''(1) SCOPE.—Each person required to register under subsection (b), (c), (d), or (i), with respect to the manufacture, preparation, propagation, compounding, or processing of a drug shall have in effect and implement a quality management plan to ensure the quality and safety of—

''(A) each such drug, including when such drug is prepared, propagated, compounded, or processed by another person;

''(B) each active and inactive ingredient of such drug, including when such ingredient is prepared, propagated, compounded, processed, or held by another person; and

''(C) materials used in the manufacture of the active ingredient, based on a risk assessment that gives additional consideration to materials extracted or derived from plants, microbes, animal tissue, or other biological sources.

''(2) PROVISIONS.—

''(A) IN GENERAL.—Each quality management plan required under paragraph (1) shall—

''(i) address risk assessment, risk control, risk communication, and risk review;

''(ii) provide for an assessment, prior to contracting with a person to supply ingredients or to undertake any aspect of the manufacturing of a drug, of the suitability and competence of such person to carry out such activity, using audits, material evaluations, or qualification, as appropriate;

''(iii) define responsibilities and communication processes for manufacturing, quality control, and quality assurance activities of any person described in clause (ii);

''(iv) provide for the monitoring and review through periodic on-site audits of the facility conditions, controls, and practices of any person described in clause (ii) and ensure the implementation of appropriate measures to improve such conditions, controls, and practices;

"(v) provide for the monitoring of incoming materials to ensure that such materials are from a person who meets the requirements under clauses (ii) through (iv);

"(vi) provide for implementation of effective systems, including appropriate specifications and test methods and verification of the identity, quality, strength, and purity of drug ingredients, to detect any hazard that has been, or is reasonably likely to be, present in or on the drug during production, manufacturing, processing, packing, holding, or transporting; and

"(vii) provide for adequate assessment of materials used in the manufacture of the active ingredient.

"(B) ADDITIONAL PROVISIONS.—If the Secretary determines that provisions in addition to those described in subparagraph (A) would be appropriate to include in quality risk management plans for the protection of the public health, including provisions for the prevention of intentional adulteration of a drug or class of drugs, the Secretary may by regulation require

that such provisions be included in quality risk management plans.

''(3) REVIEW AND UPDATING.—Each person required to implement a quality management plan under this subsection shall periodically review such plan and update such plan as necessary.

''(4) APPLICATION OF SPECIFICATIONS OR TEST METHODS BY ORDER OF THE SECRETARY.—If the Secretary finds that there is a significant threat to public health, the Secretary may order an establishment—

''(A) to promptly revise its quality risk management plan to include new or modified specifications or test methods for a drug; and

''(B) to promptly implement such specifications or test methods.

''(5) INSPECTION OF QUALITY MANAGEMENT PLAN.—The Secretary shall, in the course of an inspection under section 704 of an establishment subject to this subsection or upon request by the Secretary, conduct a review of the quality management plan of the establishment.

''(r) DOCUMENTATION OF SUPPLY CHAIN.—Each person required to register under subsection (b), (c), (d), or (i), with respect to the manufacture, preparation, prop-

agation, compounding, or processing of a drug shall provide, at the request of the Secretary, documentation of the names, addresses, phone numbers, and Global Positioning System coordinates of each producer, manufacturer, distributor, and shipper involved in the production of a drug or the production or transport of the active ingredients of a drug, and, where the assessment of materials described in subsection (q)(2)(A)(vii) is required, each producer, manufacturer, distributor, and shipper involved in the production or transport of such materials. Such documentation shall show that the drug and the ingredients of the drug were manufactured, prepared, propagated, compounded, processed, and handled in a manner ensuring the identity, safety, quality, purity, and strength of such drug.

''(s) TRACKING SYSTEMS.—Not later than 1 year after the date of enactment of the Drug Safety and Accountability Act of 2011, the Secretary shall develop and maintain information systems to track and assess every establishment that is involved in the manufacturing, preparation, propagation, compounding, or processing of a drug or active ingredient of a drug. The Secretary shall ensure the interoperability of all databases relevant to the tracking and assessment of such establishments and include in each such database the D–U–N–S number of each

such establishment required under subsection (b) to provide a D–U–N–S number.

''(t) OVER-THE-COUNTER DRUGS.—In determining, for purposes of inspection, the risk associated with a person required to register under this section, the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such person are drugs described in section 503(b).''.

(c) UNIQUE REGISTRATION NUMBERS.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended—

(1) in subsection (b)—

(A) in paragraph (1), by striking ''and all such establishments'' and inserting ''all such establishments, and the D–U–N–S number of each such establishment''; and

(B) in paragraph (2), by striking ''and all such establishments'' and inserting ''all such establishments, and the D–U–N–S number of each such establishment'';

(2) in subsection (c), by striking ''such establishment'' and inserting ''such establishment, and the D–U–N–S number of such establishment'';

(3) in subsection (d), by inserting ", and the D–U–N–S number of such establishment" after "devices"; and

(4) in subsection (i)(1)(A), by inserting "the D–U–N–S number of each such establishment," after "place of business of the establishment,".

(d) FACTORY INSPECTION.—Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended, in the first sentence, by inserting "in the United States or for import into the United States," after "to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held,".

(e) MUTUAL RECOGNITION AGREEMENT PROGRESS REPORT.—The Secretary of Health and Human Services shall, not later than 1 year after the date of enactment of this Act, issue a report that describes the progress on implementing cooperative arrangements and mutual recognition agreements relating to the regulation of drugs and good manufacturing practices entered into under section 510(i)(3) or section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)(3), 383).

(f) MANDATORY RECALL AUTHORITY FOR DRUGS.—

(1) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506C the following:

"SEC. 507. MANDATORY RECALL AUTHORITY FOR DRUGS.

"(a) ORDER TO CEASE DISTRIBUTION; NOTIFICATION; PROCESS.—

"(1) ORDER TO CEASE DISTRIBUTION; NOTIFICATION.—If the Secretary finds that there is a reasonable probability that a drug intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the drug)—

"(A) to immediately cease distribution of such drug; and

"(B) to immediately notify health professionals and hospitals and other health care facilities of the order and to instruct such professionals and facilities to cease use of such drug.

"(2) PROCESS.—The order under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance

of the order, on the actions required by the order and on whether the order should be amended to require a recall of such drug. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(b) ORDER TO RECALL.—

''(1) IN GENERAL.—If, after providing an opportunity for an informal hearing under subsection (a), the Secretary determines that the order should be amended to include a recall of the drug with respect to which the order was issued, the Secretary shall, except as provided in paragraph (2), amend the order to require a recall. The Secretary shall specify a timetable in which the drug recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

''(2) AMENDED ORDER.—An amended order under paragraph (1)—

''(A) shall—

''(i) not include recall of a drug from individuals; and

''(ii) not include recall of a drug from hospitals and other health care facilities if

the Secretary determines that the risk of recalling such drug from the facilities presents a greater health risk than the health risk of not recalling the drug from use; and

''(B) shall provide for notice to individuals subject to the risks associated with the use of such drug.

''(3) ASSISTANCE.—In providing the notice required by paragraph (2), the Secretary may use the assistance of health professionals who prescribed or used such a drug for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 705(b).''.

(2) REGULATIONS.—Until the date that the Secretary of Health and Human Services issues a final regulation to implement section 507 of the Federal Food, Drug, and Cosmetic Act (as added by paragraph (1)), the regulations on medical device recall authority in part 810 of title 21, Code of Federal Regulations, shall apply to any recall of a drug under such section 507.

(3) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(aaa) The failure to comply with an order issued under section 507.''.

(g) SUBPOENA AUTHORITY.—Section 702 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372) is amended by adding at the end the following:

''(f)(1) The Secretary may conduct investigations as the Secretary deems necessary—

''(A) to carry out the authority of the Secretary under this Act or section 351 of the Public Health Service Act; or

''(B) to determine whether any person has engaged or is about to engage in any act that constitutes or will constitute a violation of this Act or such section 351.

''(2) For the purpose of any investigation conducted under paragraph (1), the Secretary may administer oaths and affirmations, subpoena witnesses, compel the attendance of such witnesses, take evidence, and require the production of any books, papers, documents, or other materials that are relevant to the investigation.

''(3)(A) In case of contumacy or refusal to obey a subpoena issued under paragraph (2), the district court

of the United States for the judicial district in which such investigation or proceeding is conducted, or in which the subpoenaed person resides or conducts business, may issue an order requiring such person to appear before the Secretary, testify, or produce books, papers, documents, or other materials that are relevant to the investigation. All process in any such case may be served in the judicial district in which such person resides or may be found.

''(B) Any failure to obey an order issued under subparagraph (A) may be punished by the court as contempt of court.''.

(h) CIVIL PENALTIES.—

(1) IN GENERAL.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is amended—

(A) in paragraph (4), by striking ''or 505–1'' each place it appears and inserting ''505–1, or 505A'';

(B) by adding at the end the following:

''(10)(A)(i) Any manufacturer, distributor, importer, broker, or filer that violates a requirement of this Act that relates to drugs for human use (except a requirement referred to in paragraph (4) or subsection (g)) shall be liable to the United States for a civil penalty not to exceed $100,000 per violation.

''(ii) Each day during which a violation continues shall be considered a separate violation under clause (i).

''(B)(i) Any manufacturer, distributor, importer, broker, or filer that knowingly reports or enters false or misleading data on documents related to the importation of a drug shall be liable to the United States for a civil penalty not to exceed $150,000.

''(ii) Each act of reporting or entering false data shall be considered a separate violation under clause (i).''; and

(C) in paragraph (5) by striking '', or (9)'' each place it appears and inserting ''(9), or (10)''.

(2) APPLICABILITY.—Section 303(f)(10) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1), shall apply to violations described in such section that occur after the date of enactment of this Act.

(i) EXCHANGE OF INFORMATION.—

(1) IN GENERAL.—Section 708 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379) is amended—

(A) by striking ''The Secretary'' and inserting ''(a) The Secretary''; and

(B) by adding at the end the following:

''(b)(1)(A) The Secretary may provide to any Federal agency acting within the scope of its jurisdiction any information relating to drugs that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, or that is referred to in section 301(j).

''(B) Any such information provided to another Federal agency shall not be disclosed by such agency except in any action or proceeding under the laws of the United States to which the receiving agency or the United States is a party.

''(2)(A) In carrying out this Act, the Secretary may provide to a State or local government agency any information relating to drugs that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, or that is referred to in section 301(j).

''(B) Any such information provided to a State or local government agency shall not be disclosed by such agency.

''(3) In carrying out this Act, the Secretary may provide to any person any information relating to drugs that

is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, if the Secretary determines that providing the information to the person is appropriate under the circumstances and the recipient provides adequate assurances to the Secretary that the recipient will preserve the confidentiality of the information.

''(4) In carrying out this Act, the Secretary may provide any information relating to drugs that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, or that is referred to in section 301(j)—

''(A) to any foreign government agency; or

''(B) any international organization established by law, treaty, or other governmental action and having responsibility—

''(i) to facilitate global or regional harmonization of standards and requirements in an area of responsibility of the Food and Drug Administration; or

''(ii) to promote and coordinate public health efforts,

if the agency or organization provides adequate assurances to the Secretary that the agency or organi-

zation will preserve the confidentiality of the information.

''(c) Except where specifically prohibited by statute, the Secretary may disclose to the public any information relating to drugs that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, if the Secretary determines that such disclosure is necessary to protect the public health.

''(d) Except as provided in subsection (e), the Secretary shall not be required to disclose under section 552 of title 5, United States Code, or any other provision of law any information relating to drugs obtained from a Federal, State, or local government agency, or from a foreign government agency, or from an international organization described in subsection (b)(4), if the agency or organization has requested that the information be kept confidential, or has precluded such disclosure under other use limitations, as a condition of providing the information.

''(e) Nothing in subsection (d) authorizes the Secretary to withhold information from the Congress or prevents the Secretary from complying with an order of a court of the United States.

''(f) This section shall not affect the authority of the Secretary to provide or disclose information under any other provision of law.''.

(2) CONFORMING AMENDMENT.—Section 301(j) (21 U.S.C. 331(j)) is amended by striking ''or to the courts when relevant in any judicial proceeding under this Act,'' and inserting ''to the courts when relevant in any judicial proceeding under this Act, or as specified in section 708,''.

(j) WHISTLEBLOWER PROTECTION.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

''SEC. 1013. PROTECTIONS FOR EMPLOYEES WHO REFUSE TO VIOLATE, OR WHO DISCLOSE VIOLATIONS OF, THIS ACT OR SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT.

''(a) IN GENERAL.—

''(1) PROTECTIONS FOR EMPLOYEES.—No person that submits, or is required to submit to the Secretary a submission described in paragraph (2), or any officer, employee, contractor, subcontractor, or agent of such a person, may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in the terms and conditions of employment because of any lawful act

done by the employee, including within the ordinary course of the job duties of such employee—

"(A) to provide information, cause information to be provided, or otherwise assist in any investigation regarding any conduct which the employee reasonably believes constitutes a violation of any section of this Act or the Public Health Service Act described under paragraph (2), any other provision of Federal law relating to the safety or effectiveness of a drug, biological product, or device, or any provision of Federal law prohibiting fraud against the Food and Drug Administration, if the information or assistance is provided to, or an investigation stemming from the provided information is conducted by—

"(i) a Federal regulatory or law enforcement agency;

"(ii) any Member of Congress or any committee of Congress; or

"(iii) a person with supervisory authority over the employee (or such other person working for the employer who has the authority to investigate, discover, or terminate the misconduct);

''(B) to file, cause to be filed, testify, participate in, or otherwise assist in a proceeding filed or about to be filed (with any knowledge of the employer) relating to an alleged violation of any section of this Act or the Public Health Service Act described under paragraph (2), any other provision of Federal law relating to the safety or effectiveness of a drug, biological product, or device, or any provision of Federal law prohibiting fraud against the Food and Drug Administration; or

''(C) to refuse to violate or assist in the violation of any section of this Act or the Public Health Service Act listed described paragraph (2), any other provision of Federal law relating to the safety or effectiveness of a drug, biological product, or device, or any provision of Federal law prohibiting fraud against the Food and Drug Administration.

''(2) SUBMISSION.—A submission described in this paragraph is—

''(A) a new drug application under section 505(b);

''(B) an abbreviated new drug application under section 505(j);

"(C) a biologics license application under section 351 of the Public Health Service Act;

"(D) an application for an investigational new drug exemption under section 505(i);

"(E) a new animal drug application under section 512(b);

"(F) an abbreviated new animal drug application under section 512(b);

"(G) an application under section 571;

"(H) a request under section 572;

"(I) an application or report for premarket approval under section 515;

"(J) an application for an investigational device exemption under section 520(g);

"(K) a report under section 510(k);

"(L) an application for a humanitarian device exemption under section 520(m);

"(M) an amendment, supplement, or other submission with respect to any such application or report described in subparagraphs (A) through (L); or

"(N) a record or report related to an adverse event, a postapproval study, a postapproval clinical trial, a report, or postmarket

surveillance under section 505(k), 505(o), 519, 522, or 760.

''(b) ENFORCEMENT ACTION.—

''(1) IN GENERAL.—An employee who alleges discharge, or other discrimination in violation of subsection (a), may seek relief in accordance with the provisions of subsection (c), by—

''(A) filing a complaint with the Secretary of Labor; or

''(B) if the Secretary of Labor has not issued a final decision within 210 days of the filing of the complaint and there is no showing that such delay is due to the bad faith of the claimant, bringing an action at law or equity for de novo review in the appropriate district court of the United States, which shall have jurisdiction over such an action without regard to the amount in controversy.

''(2) PROCEDURE.—

''(A) IN GENERAL.—Any action under paragraph (1) shall be governed under the rules and procedures set forth in section 42121(b) of title 49, United States Code.

''(B) EXCEPTION.—Notification in an action under paragraph (1) shall be made in ac-

cordance with section 42121(b)(1) of title 49, United States Code, except that such notification shall be made to the person named in the complaint and to the employer.

''(C) BURDENS OF PROOF.—An action brought under paragraph (1)(B) shall be governed by the legal burdens of proof set forth in section 42121(b) of title 49, United States Code.

''(D) STATUTE OF LIMITATIONS.—An action under paragraph (1) shall be commenced not later than 180 days after the date on which the violation occurs.

''(c) REMEDIES.—

''(1) IN GENERAL.—An employee prevailing in any action under subsection (b)(1) shall be entitled to all relief necessary to make the employee whole.

''(2) COMPENSATORY DAMAGES.—Relief in an action under subsection (b) shall include—

''(A) reinstatement with the same seniority status that the employee would have had, but for the discrimination;

''(B) the amount of backpay owed to the employee, with interest; and

"(C) compensation for any special damages sustained as a result of the discrimination, including litigation costs, expert witness fees, and reasonable attorney fees.

"(d) RIGHTS RETAINED BY EMPLOYEE.—Nothing in this section shall be deemed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement. The rights and remedies in this section may not be waived by any agreement, policy, form, or condition of employment.".

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